Small scale drugs units

693. SHRI MAHENDRA MOHAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware that small scale units manufacturing drugs are being closed due to stringent norms proposed for these units;

(b) how many such units have been closed in North India and Mumbai for not meeting the norms as prescribed;

(c) whether it is a fact that big companies have vested interests and want small scale units out of business;

(d) if so, whether Government would consider providing soft loans to these units so that they can fulfill minimum norms; and

(e) if not, the reasons therefor?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) Quality and safety of drugs depends on Good Manufacturing Practices. These are prescribed in Schedule M of the Drugs & Cosmetics Rules. These have to be followed by all drug manufacturing units including small scale Industries in the country.

Good Manufacturing Practices (GMP) were revised and upgraded in consultation with all stakeholders involved including the Small Scale Industries in 2000-2001. The concerns expressed during the draft stage were taken into account and incorporated in final Notification *vide* GSR 894 (E) dated 11.12.2001. Subsequently, based on consideration of representation from Small Scale industry, further relaxations were given *vide* GSR 431 (E) dated 30.06.2005.

Some manufacturers may find it difficult to follow the norms of Schedule M and to be able to manufacture quality and safe drugs. However, large numbers of manufacturers have complied with or are complying with the norms of Schedule M. These provisions are enforced by the State Drug Control Authorities.

(b) (1) In Mumbai, 47 firms have been closed till date.

(2) Information available with this office upto year 2006 regarding North India is given in the Statement (*See* below).

(c) No such information is available with this office.

(d) and (e) The matter pertains to the Ministry of Chemical and Petro Chemicals and Department of Small Scale Industry. The necessary information is being collected from the respective Ministry.

Statement

Status of compliance of revised schedule 'M' by drug manufacturing units in North India

State	Drug manufacturing units having their own premises	Drug manufacturing units complying to Schedule M requirements	Drug manufacturing units to whom notices have been served for not complying to Schedule M	Drug manufacturing units wherein compliance of Schedule M is under progress	Drug manufacturing units not complying to Schedule M requirement	Drug manufacturing units closed down manufacturing activity due to non-compliance of Schedule M
Uttaranchal	19					8
Delhi	108					
Uttar Pradesh	496	126			370	
Himachal Pradesh	85		1			1
Haryana		70		71		89